



Parliamentary Dialogue on equitable access to Oral PrEP within the EU and beyond

16 November 2022

Meeting report

Background

On 16 November 2022, The European Parliament's Intergroup on LGBTI Rights, in partnership with UNAIDS, AIDS Action Europe, Aidsfonds, European AIDS Treatment Group, and the European Public Health Alliance organised a policy dialogue on *measures to be taken to scale up equitable access to Oral Pre-Exposure Prophylaxis (PrEP) for HIV as part of HIV prevention combination strategies within the EU and beyond*. Oral PrEP, as a tool in combination prevention strategies, can be a gamechanger in helping EU member states achieve the 2030 targets on Ending AIDS. It can also a pathway for equitable and affordable access to novel health technologies within the EU and in partner countries.

Therefore, in the run-up to World AIDS Day, the European Parliament's Intergroup on LGBTI Rights and partners brought together various stakeholders - Members of the European Parliament, the European Commission, EU and UN health agencies, representatives from communities lacking access to PrEP and civil society groups - to discuss the challenges faced by populations most affected by HIV in accessing PrEP. The participants also discussed the EU's role as it is building the European Health Union.

1. Setting the scene: Access to PrEP within the EU

After introducing the meeting, **Marc Angel, Member of the European Parliament, Co-President of the Parliamentary Intergroup on LGBTI Rights**, stressed that equitable access to affordable oral PrEP is essential as part of combination prevention to end for the AIDS pandemic. Highlighting inequity in access, he urged the EU and EU Member States to remove the financial and structural barriers for all those at risk of HIV so that the EU reaches the "10-10-10" societal enabler targets and the 2030 goal of ending AIDS: "Less than 10% of countries have punitive legal and policy environments that deny access to justice. Less than 10% of people living with HIV and key populations experience stigma and discrimination. Less than 10% of women, girls, people living with HIV and key populations experience gender inequality and violence."¹

Then **Jantine Jacobi** from **UNAIDS** provided a -global update. In 2021, 38.4 million people were living with HIV, with 1.5 million new HIV infections in 2021 and 650 000 deaths due to AIDS in 2021. New infections per region show a persistent increase in annual HIV infections in eastern Europe and Central Asia, the Middle East and North Africa, and Latin America. New infections are equally distributed by population groups, but the risks are higher when people are criminalised, in young girls (15-24) and women in sub-Saharan Africa.

¹ End Inequalities. End AIDS. Global AIDS Strategy 2021–2026. <https://www.unaids.org/en/resources/documents/2021/2021-2026-global-AIDS-strategy>

UNAIDS urges the EU, governments, and donors to increase investments to scale up HIV prevention so that it reaches people at higher risk of HIV with support of civil society and community networks; to address underlying inequalities and barriers to services; to ensure equitable access to affording health technologies.

Jantine Jacobi then presented data from the **European Centre on Disease Prevention and Control (ECDC)**'s monitoring on access to oral PrEP for HIV within the EU, which highlights significant inequity in its delivery and gaps in access. In 2019, it was estimated that 500.000 of gay, bisexual, and other men who have sex with men (MSM) who would like to access PrEP cannot access it, leaving a 17% gap². Moreover, there are important price differences across the EU, generic PrEP price varies from €5 to €434 whilst branded PrEP, from €200 to €6.041.

Thus, drawing from its findings ECDC highlights that:

- PrEP is very effective at preventing HIV-negative people from acquiring HIV. It is an essential element in the 'combination prevention' necessary to reach the United Nations Sustainable Development Goal (SDG) of ending the AIDS epidemic by 2030.
- There has been an increase in implementing PrEP, either as part of national healthcare provision or in implementation studies.
- Greater access to PrEP and progress in PrEP implementation are needed to reach the SDG of ending the AIDS epidemic by 2030. To achieve this progress, it would be helpful for countries to gain a better understanding of the barriers, within their country, to implementing PrEP programmes.
- Certain key populations, such as people who inject drugs, prisoners, and undocumented migrants, remain ineligible for PrEP in many countries in the European Region. PrEP eligibility requirements may restrict certain individuals from accessing PrEP. Countries should review PrEP eligibility, considering the HIV prevalence and all relevant key populations.
- Countries are encouraged to share experiences on feasibility of implementation, costs and technical capacity with those countries that have not implemented national PrEP guidelines.
- Strong surveillance systems would enable data on PrEP eligibility, uptake, duration and outcomes to be captured. Consistent data collection across the Region should be encouraged. In particular, the extent of informal online access to PrEP and the relevant health outcomes should be added to existing monitoring.
- Improved data collection and surveillance on PrEP uptake are vital for obtaining a proper understanding of who has access PrEP. In addition, best practices need to be shared, especially those relating to feasibility, cost, and technical matters, to support the roll-out of PrEP in the Region.

Nina Tumanyan, AIDS Action Europe presented then the findings and recommendations from civil society organisations survey on PrEP and practical access challenges.

- Countries that have no reimbursement schemes for PrEP have unofficial access to PrEP with people purchasing PrEP online or from the neighbouring countries and there are missed opportunities for HIV and STI (Sexually Transmitted Infection) testing and diagnosis.
- A good example of community-based service-delivery from Sofia checkpoint prescribing 95% of PrEP in Bulgaria.

Countries that reimburse:

- Restrictive eligibility criteria and long waiting list to get a prescription for PrEP.
- Challenges in accessing PrEP for people that are not covered by insurance, and unofficial access tends to be restricted, leaving behind people not covered by eligibility criteria

Common findings:

² Hayes Rosalie, et al. Estimating the 'PrEP Gap': how implementation and access to PrEP differ between countries in Europe and Central Asia in 2019. Euro Surveill. 2019;24(41):pii=1900598. <https://doi.org/10.2807/1560-7917.ES.2019.24.41.1900598>

- The prices of PrEP in EU/EEA countries are still remarkably high, even for generics.
- PrEP is more easily accessible in urban areas.
- Information campaigns on PrEP are often led by NGOs who might not have enough financial support. There is an almost non-existent campaign backed up by public money or public health campaigns.
- PrEP-related services and information target young educated MSM; while vulnerable groups such as migrants, bisexual MSM, women, women with migration backgrounds, trans people, and sex workers are left behind.

Therefore, to reach the 2030 targets, AIDS Action Europe stresses the urgent need to ensure universal, free, and low-threshold access to PrEP and to make it available to everyone who might benefit from it. It also calls on public health authorities to include PrEP as an HIV combination prevention, prioritise national healthcare strategies, make the eligibility criteria more inclusive and develop awareness-raising campaigns that better target on communities that are currently left behind. Moreover, cross-sectoral collaboration between community and medical health care providers is necessary to address the PrEP access barriers related to prescribing privileges, stigma, and discrimination.

2. Community testimonies on challenges faced in accessing oral PrEP

During this session, representatives from populations lacking access to PrEP programmes shared specific challenges faced by the communities and their demand to policy makers and healthcare providers.

Attila Krsjak, volunteer at the **Altalap Foundation** and member of the **European AIDS Treatment Group** presented on lack of access to PrEP in Hungary. PrEP is not reimbursed in Hungary, and only available via prescription from specialists at a limited number of clinics. Due to high demand, lack of capacity and long wait-times, there is a growing trend of people purchasing PrEP online. This informal use compromises the ongoing testing and monitoring that is required for safe PrEP use. There is also a larger issue regarding limited HIV testing availability and uptake, which is skewing estimates of HIV incidence in Hungary. Some experts estimate prevalence to be significantly higher. Since prevalence is officially low then there is no investment in prevention. In that context, the goal of community actors are channel PrEP users to the formal and public health system. In the short term, it is important to make healthcare providers ready to deliver PrEP. Generic PrEP must be available for free or reduced price through the public health system to the public in Hungary to prevent HIV infections.

Amanita Calderon Cifuentes, **Transgender Europe** followed with an intervention on access barriers for Transgender people in Europe. HIV continues to disproportionately affect transgender people worldwide. Globally, HIV prevalence estimates among trans women is 19.9%, and 2.6% for trans men is 2.6%. Trans women have a 14 times higher risk of acquiring HIV compared to cisgender women, and 66 higher odds of being infected than the general population³. PrEP is often at a price the poorest cannot afford. Transphobia and cisnormativity represents barriers to accessing PrEP for trans people, as issues such as misgendering and deadnaming are repeatedly committed in healthcare settings. Amanita advocated for stronger anti-discrimination laws and policies to protect key populations, training of healthcare professionals on matters of gender identity and gender expression, and funding for community-led monitoring programmes of discrimination cases. She also pointed the need for greater inclusiveness in research and development for PrEP (looking for instance at the interactions between ARVs, PEP, PrEP, and hormonal substitution therapy). She called for easier access to PrEP for trans people and all other key populations regardless of their residency or health insurance status and capacity to buy the medication.

Grâce Ntunzwenimana, **Plateforme Prevention Sida** drew her presentation from a project on migrant access to PrEP in Brussels, Belgium. Its findings indicate that women who may benefit from PrEP lack information. The persons who are supposed to inform them about PrEP do not have enough knowledge about it or think that the women are not going to take it correctly. Given this, and the challenges faced by women in negotiating sexual

³ Stutterheim SE, van Dijk M, Wang H, Jonas KJ (2021) The worldwide burden of HIV in transgender individuals: An updated systematic review and meta-analysis. PLoS ONE 16(12): e0260063. <https://doi.org/10.1371/journal.pone.0260063>

health practices with partners, long-acting Injectable PrEP could be a better avenue for migrant women's PrEP access. Migration is a risk factor and a vulnerable moment, and the data shows that most migrants in Europe living with HIV, have acquired HIV post-migration⁴. Migrant women and MSM are in need of PrEP. In Belgium, people who are undocumented can access HIV treatment at no cost but not PrEP. There is the need for collaboration among health clinics and community-based organisations to facilitate easier access to PrEP for migrants. Universal access to prevention is essential and we cannot wait until people are infected to provide them with HIV-related care.

Luca Stevenson, European Sex Workers' rights Alliance

Only 18 EU countries make PrEP accessible to sex workers; however, most sex workers do not have access to PrEP. Sex workers are not a monolithic group, and every sub-group has specific HIV prevention needs and preferences. Stigma and criminalisation of sex work have a direct impact on PrEP service delivery and access to sex workers. One of the biggest social determinants of health impacting sex workers is poverty and lack of social protections. Luca called on governments to listen to sex workers and develop programmes in partnership with sex worker-led organisations and carry out research on health inequalities and the overlapping needs among key populations. He also stressed that sex worker's rights-led organisations are essential to make PrEP more accessible, however these must be resourced accordingly to deliver services, be involved in research and advocacy for the rights of sex workers. France and Sweden criminalise sex work which puts the safety of sex workers at risk, and they continue to promote this agenda in other countries. At the same, there is also progress as Belgium recently decriminalised sex work in recognition of the needs of sex workers after talking with them. It is important that Members of the European Parliament continue dialogue with sex workers. He noted that the European Commission made a recommendation that includes sex workers in its proposal on combating violence against women and domestic violence⁵. Luca hopes that the European Commission and MEPs' discourse on sex work moves forward in a manner that does not conflate sex work with violence against women.

3. Moderated dialogue on how to ensure equitable access to PrEP

Tilly Metz, Member of the European Parliament stressed that there is an urgent need to provide training to healthcare providers, and to listen carefully to community needs. A comprehensive approach and continuity of care are crucial. She drew attention to the EU joint procurements of COVID-19 vaccines. She also highlighted the need to re-balance negotiating power between pharma companies and public authorities. She noted the issue of significant price differences between member states and called for greater transparency of prices and of research and development costs. This in turn will give more negotiating power to EU countries and ensure PrEP is equitably distributed and affordable in Europe. Transparency has a direct link to affordability and accessibility. She also indicated a review of the pharmaceutical legislation to increase price transparency, but it is not on the table of discussion.

Cyrus Enger, Member of the European Parliament expressed appreciation for the critical input of civil societies and people working on the ground in policy work. Intersectionality needs to be incorporated into health services as a wider population needs access to PrEP, not only MSM. Accessible PrEP at an affordable price for all needs to be a priority for the accomplishment of the right to health. Joint procurement is a solution, and we can look to the learnings of joint procurement of Covid-19 vaccines as a way forward. We must ensure that the voices of migrant populations, the transgender community, sex workers and persons living in rural areas amongst others, are heard in this collective fight.

Rimalda Voske from the European Commission Directorate General Responsible for health (SANTE) outlined a number of EU public health activities which could contribute to this issue. She acknowledged the latest ECDC data showing that a wider scale implementation of evidence-based high-impact prevention, including PrEP services, is vital to accelerate progress towards the Sustainable Development Goals (SDGs) and recalled that the Commission

⁴ Christiana Nöstlinger, Theo Cosaert, Ella Van Landeghem, Jef Vanhamel, Gary Jones, Dominik Zenner, et al., HIV among migrants in precarious circumstances in the EU and European Economic Area, *The Lancet HIV*, ISSN: 2352-3018, Vol: 9, Issue: 6, Page: e428-e437.

⁵ Proposal for a Directive of the European Parliament and of the Council on combating violence against women and domestic violence, COM/2022/105 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0105>

supports EU Member States in this endeavour. She referred to ECDC's minimum standards on the principles of PrEP programming, monitoring and surveillance, which should be considered by countries when developing and implementing national guidelines, including increasing PrEP accessibility for all key populations. She stressed the need to find effective ways of communicating with vulnerable populations to find workable solutions, and there is a wide recognition (including by ECDC, UNAIDS and WHO) that community services and organisations are crucial in this dialogue, as well as in broadening the reach of services to the key populations, advancing human rights and combatting stigma and discrimination. To this end, the Commission is investing over 7.5 million euros under the EU4Health Programme in 5 community-based projects that will work to help people who are disproportionately affected by HIV/AIDS, viral hepatitis, tuberculosis and sexually transmitted infections to easier access quality services, as well as in operating grants supporting community organizations working on responses to these diseases. The Commission fosters the access of health services in national health systems via the European Semester process and via the Recovery and Resilience Facility, as well as supports the scale up of good practices. She also noted the expanding mandate of the Steering Committee on Health Promotion and Diseases to other persistent public health issues, such as communicable diseases, antimicrobial resistance and vaccination strategies; as well as the thematic network on HIV, TB and viral hepatitis on the EU Health Policy Platform. This Network will issue joint statements including actions to be put by and for the health stakeholders and the interested community organizations can contribute to this work. Lastly, she referred to the results of the stakeholder consultation when preparing the Global Health Strategy, where stakeholders urged the need to strengthen efforts on prevention to reach the SDGs, including the target to end the AIDS epidemic by 2030, as well as clarified a voluntary nature of the Joint Procurement Agreement mechanism for cross-border health threats.

Viatecheslav Grankov, WHO Europe drew attention to the WHO implementation guidance for simplified and differentiated service delivery of PrEP, in-line with community speakers' demand for decentralised and community-based PrEP delivery.

Dimitri Eynikiel, from Médecins Sans Frontière, reminded the group that one of the barriers to PrEP has been the patent supplementary certificate. Some countries were able to access generic versions of Emtricitabine/tenofovir because they had not granted this patent extension. He stressed that the unitary patent proposal would prevent this possibility.⁶

Pierre Karleskind, Member of the European Parliament, closed the session by noting that PrEP is one of the key solutions available to prevent new HIV infections, however the ongoing discrepancy in access to PrEP for people living in the EU must be addressed. The EU and its member states agreed to purchase together 2 billion COVID-19 vaccines. The EU could jointly procure HIV prevention drugs as necessary to ensure "free oral PrEP" by 2025 to 1 million people in the EU. Furthermore, PrEP is more than just taking a pill, it is an integrated intervention that requires routine STIs screening and continued care. Self-testing is an additional testing option to be considered to increase testing access and uptake. He also called for continued funding for the Global Fund.

⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Making the most of the EU's innovative potential An intellectual property action plan to support the EU's recovery and resilience, COM/2020/760 final, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52020DC0760> ; MSF 2022, Cabotegravir: What are we waiting for. <https://msfaccess.org/cabotegravir-what-are-we-waiting>; Yuanqiong H., Eynikel D. , Pascale Boulet P, Krikorian G., Supplementary protection certificates and their impact on access to medicines in Europe: case studies of sofosbuvir, trastuzumab and imatinib, Hu et al.